The State Pharmacopoeia of the Republic of Kazakhstan

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The State Pharmacopoeia of the Republic of Kazakhstan (SPRK)

- Approved in 2008 by the Order of the Ministry of Health
Harmonization of requirements for quality and safety of medicines

Recognition of European Pharmacopoeia, United States Pharmacopoeia, British Pharmacopoeia, German Homeopathic Pharmacopoeia, which were introduced into action by the Order of the Pharmacy Committee of the Ministry of Health of the Republic of Kazakhstan (February, 2004)

Continuity of principles and application of methods of the European Pharmacopoeia in development of the SPRK

Entry of Kazakhstan as an observer of European Pharmacopoeial Commission (June, 2006)

Entry of Kazakhstan as an observer (July, 2009) and a Voting Member (November, 2010) of U.S. Pharmacopoeial Convention

Signing the Grant of Rights to Copy and Adapt the USP-NF agreement (October, 2010)
SPRK Structure

Volume 1
General chapters and monographs

Volume 2
Monographs on pharmaceutical substances, dosage forms, herbal drugs, vaccines for human use, human immunoglobulins
Number of texts included in the SPRK

- Pharmaceutical substances (API and Excipients) 300
- Dosage forms 77
- Herbal drugs 26
- Vaccines for human use, human immunoglobulins 15
- General monographs 221
SPRK Monograph Structure

Monograph

General (European) Part:
Requirements of the European Pharmacopoeia

National Part:
Requirements of the SP USSR,
National requirements for quality and safety of medicines
General (European) Part

- Contains requirements for quality of medicines produced in accordance with the GMP rules
- Closely follows the format of the European Pharmacopoeia
- Adapted to country-specific context and conforms with national regulatory requirements
National Part

- Contains requirements to quality of medicines non-compliant to GMP rules
- Includes alternative procedures, additional requirements and information materials
- Does not contradict European part, but supplements it
Publication of harmonized pharmacopoeial texts within the SPRK

- Number of texts: 639
- Number of national texts: 100
- Number of harmonized texts: 539

- General chapters and monographs
- Monographs on pharmaceutical substances
- Monographs on vaccines for human use and human immunoglobulins
Strategy for the future

- Introduction of the SPRK standards in a pharmaceutical area
- Further harmonization with EP and USP
- Development and edition of the III volume with the new monographs (2012-2013)
- Revision of the monographs in the 2nd edition of the SPRK (2014-2016)
Thank You for Your Attention!